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David R. Saliwanchik, Patent Attorney

INFORMATION DISCLOSURE **STATEMENT** Examining Group 1646

Patent Application Docket No. GJE-6089D2

Serial No. 10/658,219

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit

1646

Applicant

Bruce Joseph Roser

Serial No.

10/658,219

Filed

September 8, 2003

For

Dried Blood Factor Composition Comprising Trehalose

Mail Stop DD Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313

INFORMATION DISCLOSURE STATEMENT UNDER 37 CFR §§1.97 AND 1.98

Sir:

In accordance with 37 CFR §1.56, the references listed on the attached form PTO/SB/08 are being brought to the attention of the Examiner for consideration in connection with the examination of the above-identified patent application. A copy of each cited reference is enclosed.

The applicant respectfully asserts that the substantive provisions of 37 CFR §§1.97 and 1.98 are met by the foregoing statement.

Respectfully submitted,

David R. Saliwanchik

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DRS/la

Attachments: Form PTO/SB/08; copies of references cited therein.

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PTO/SB/08A (08-03)

Approved for use through 07/31/2006. OMB 0651-0031
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| Substitute for form 1449A/PTO | | | | Complete if Known | | |
|---|---|----|---|-------------------------------|--------------------|--|
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary) | | | | Application Number | 10/658,219 | |
| | | | | Filing Date September 8, 2003 | | |
| | | | | First Named Inventor | Bruce Joseph Roser | |
| | | | | Art Unit | 1646 | |
| | | | | Examiner Name | Not yet assigned | |
| Sheet | 1 | of | 2 | Attorney Docket Number | GJE-6089D2 | |

| U.S. PATENT DOCUMENTS | | | | | |
|-----------------------|---------------|--|--------------------------------|---|---|
| Examiner Initials* | Cite No. 1 | Document Number Number - Kind Code ² (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear |
| | U1 | US-4,495,175 A | Chavin et al. | 1-22-1985 | |
| | U2 | US-4,758,657 A | Farb et al. | 7-19-1988 | |
| | U3 | US-4,806,343 A | Carpenter et al | 2-21-1989 | |
| | U4 | US-4,891,319 A | Roser | 01-02-1990 | |
| | U5 | US-5,364,756 A | Livesey et al. | 11-15-1994 | |
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| | U7 | US-6,649,386 B2 | Roser | 11-18-2003 | |
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| | U9 | US- | | | |

| FOREIGN PATENT DOCUMENTS | | | | | | |
|--------------------------|---------------|---|--------------------------------|--|---|----------------|
| | | Foreign Patent Document | | | Pages, Columns, Lines, | |
| Examiner Initials* | Cite No. 1 | Country Code ³ - Number ⁴ - Kind Code ⁵ (if known) | Publication Date MM-DD-YYYY | Name of Patentee or Applicant of Cited Document | Where Relevant Passages or Relevant Figures Appear | T ⁶ |
| | F1 | EP 0 314 095 A1 🦻 | 05-03-1989 | Rorer International (Overseas) Inc. | | |
| | F2 | EP 0 475 409 A2 👂 | 03-18-1992 | Lifecell Corporation | | |
| | F3 | WO 87/00196 | 01-15-1987 | Quadrant Bioresources Limited | | |
| | F4 | WO 94/07510 A1 | 04-14-1994 | Kabi Pharmacia AB | | |
| | F5 | WO 95/01804 ♀ | 01-19-1995 | Kabi Pharmacia AB | | |
| | F6 | WO 95/07713 ✓ | 03-23-1995 | Baxter International | | |
| | F7 | | | | | |

| [Examiner | Date |
|------------|------------|
| Signature | Considered |

^{*}EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. Applicant's unique citation designation number (optional). See Kind Codes of USPTO Patent Documents at www.uspto.gov or MPEP901.04. Enter Office that issued the document, by the two-letter code (WIPO Standard T.3). For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.97 and 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the This collection of information is required by 37 CFR 1.37 and 1.96. The information is required to obtain or retain a definition by the public writer is to the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 2 hours to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

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C mplete if Known Substitute for form 1449B/PTO **Application Number** 10/658,219 INFORMATION DISCLOSURE **Filing Date** September 8, 2003 STATEMENT BY APPLICANT First Named Inventor Bruce Joseph Roser **Group Art Unit** 1646 (use as many sheets as necessary) **Examiner Name** Not yet assigned Sheet of **Attorney Docket Number** GJE-6089D2

| NON PATENT LITERATURE DOCUMENTS | | | | | |
|---------------------------------|---------------|--|----------------|--|--|
| Examiner Initials* | Cite No. 1 | Include name of the author (in CAPITAL LETTERS), title of the article, (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² | | |
| | R1 | Cleland, J.L. et al. (ed) "Design and Development Strategies" Chapter 1 in Formulation and Delivery of Proteins and Peptides, American Chemical Society Symposium Series (1994) 567:1-19. | | | |
| ٠ | R2 | Roser, B. et al. "Trehalose Drying: A Novel Replacement for Freeze-Drying" BioPharm (September 1991) vol. 4(8):47-53. | | | |
| | R3 | | | | |
| | R4 | | | | |
| | R5 | | | | |
| | R6 | | | | |
| | R7 | · | | | |
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| | R10 | | | | |
| | R11 | · · · · · · · · · · · · · · · · · · · | | | |
| | R12 | | <u> </u> | | |
| | R13 | | † <u> </u> | | |

| | | |
|-----------|----------------|--|
| Examiner | Date | |
| Signature | Considered | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

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